REMARKS

Claims 82-85 have been amended to address the rejection of claims 82 and 84 under 35 USC 112, second paragraph. Applicant respectfully suggests that these issues are now moot.

Claims 75, 77-90 and 99-102 stand rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,198,193 to Bunce et al. (hereinafter "Bunce et al.) or by U.S. Patent No. 5,275,785 to May et al. (hereinafter "May et al."). Claims 92-98 stand rejected under 35 USC 103(a) as being obvious over Bunce et al. or May et al. further in view of U.S. Patent No. 5,939,331 to Burd et al. (hereinafter "Burd et al.") Applicant has amended claim 75 to more particularly define the present invention over the cited prior art.

More particularly, amended claim 1 recites, *inter alia*,

> ... said detection zone being manually moveable from a first position in communication with said first flow path to a second position in communication with said second flow path;
>
> wherein when said detection zone is in its first position **said sample receiving zone is spaced downstream from said detection zone along said first flow path** and there is flow of said sample in said mobile phase from said sample receiving zone to said detection zone, whereby said analyte is allowed to substantially bind with said immunoadsorbent, when said analyte is present in said sample; and **when said detection zone is in its second position there is flow of said labeled immunoreactive material in said mobile phase to said detection zone without passing through said sample receiving zone**, whereby said labeled immunoreactive material is allowed to substantially bind to said analyte, when said analyte has bound to said immunoadsorbent, so as to provide an indication of the presence of said analyte in said sample.

Nowhere does the cited prior art teach or suggest these features.

Bunce et al. discloses a liquid transfer device for use in assaying samples, the device including two liquid flow channels. The flow channels originate at a mobile reservoir 60a and lead to a sample receiving/analysis zone 31a. The flow channels include respective reagent zones 11a and 21a. In operation, a sample is supplied to the sample receiving/analysis zone 31a where antigens of interest are bound by antibodies. In all of the embodiments disclosed in Bunce et al., the sample to be tested is supplied to the sample receiving/analysis zone 31a and reactants are carried along the respective flow paths from the reagent zones 11a, 21a to the sample receiving/analysis zone 31a. There is no teaching or suggestion in Bunce et al. for the apparatus to be configured to allow immunoreactive material to flow to a detection zone and bypass the sample receiving zone as required by amended claim 1. Furthermore, there is no teaching or suggestion in Bunce et al. for the apparatus to be configured to provide a sample receiving zone that is spaced downstream from the detection zone along the first flow path as required by amended claim 1.

Furthermore, the apparatus of Bunce et al. employ a "porous material in a compacted form expansible upon hydration" is used either to bridge a gap in flow channels, or as a switch to change the flow of material between different flow channels. It is clear that it is this expansion of the hydrated material that is responsible for the fluid connection of the flow channels. There is no manual movement of a detection zone between flow paths as recited in amended claim 75. Instead, the detection zone of Bunce

et al. is stationary and always connected to one of the two flow paths. Indeed, from the "background of the invention" in column 1 of this document it is clear that the devices of Bunce et al. are intended to avoid the perceived difficulties associated with the use of devices involving "complex manual procedures". This use of hydratable expansible materials is intended to render manual movement of portions of the device unnecessary. In light of the above, amended claim 75 is clearly patentable over the disclosure of Bunce et al.

May et al. described a device that uses a "liquid-swellable material" to make contact between two liquid-conductive channels (see lines 1 to 5 of column 2). May et al. does not, contrary to the Examiner's suggestion, consider a "manually moveable" detection zone. Instead, the device of May et al. employs a stationary detection zone 8 that is always connected to the reactant carrying channel 3. Moreover, the device of May et al. employs a sample reservoir 6 that acts as a source of sample and mobile phase to both fluid channels. In contrast, the present invention of claim 1 employs a sample receiving zone as part of the first flow path as well as a mobile phase receiving zone that is spaced downstream from the sample receiving zone along the first flow path. This configuration operates in a significantly different manner that that described in May et al. In light of the above, amended claim 75 is clearly patentable over the disclosure of May et al.

Burd et al. does not remedy the shortcomings of Bunce et al. and May et al.

It is clear from consideration of Bunce et al., May et al. and Burd et al., that the devices described therein are not suitable for manual movement between flow paths. Instead, movement is controlled entirely by hydration and swelling of a material incorporated in the flow path. It is this swelling which causes movement within the device. Were an operator to attempt to manually switch between flow paths before hydration and swelling of the material, this would cause damage of the material, and would prevent function of the flow path as required. Similarly, the operator cannot readily prevent or delay such switching once hydration of the expandable material has occurred.

Applicant note that that manually moveability of the detection zone provides significant advantages that are not afforded by the cited prior art.

More specifically, manually moveability of the detection zone provides greater "flexibility" for the first incubation. This helps to improve sensitivity and allows thorough "washing" of the detection zone to remove excess analyte and other interfering molecules. Flexibility of this sort cannot be provided by the cited prior art devices. These devices are intended to remove the element of human control and intervention in determining incubation times, instead relying on a "built in" time determined and controlled by selection of the materials used in manufacture. The inability to control incubation times, and thus the degree of "washing" to be achieved, may lead to a high dose hook effect that significantly detracts from the accuracy of the assay.

Manually moveability of the detection zone also enables a completely separated second incubation stage, which allows the particulate reagent to progress along the detection zone in a bolus unaffected by analyte/interfering agents, thus reducing the likelihood of unwanted prozone or hook effects and improve sensitivity. This advantage is considered, for example, in the second paragraph (lines 14 to 21) of page 11 of the specification as filed, and in lines 1 to 3 of page 14.

The dependent claims 77, 79-90, 92-102 and 106 are patentable over the cited prior art for those reasons advanced above with respect to claim 75 and for reciting additional features that are neither taught or suggested by the cited prior art.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

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March 13, 2008